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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,640	04/20/2007	Alexander Mackerell	100413-5018	1522

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EXAMINER	
POLANSKY, GREGG	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,640	MACKERELL ET AL.	
	Examiner	Art Unit	
	GREGG POLANSKY	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 2, 4-13, 15, 16, 18, 19, 21 and 22, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain thereof, comprising administering an effective amount of a compound of formula I or a pharmaceutically acceptable salt thereof.

Group II, claims 1, 2, 4-13, 18, 19, 21 and 22, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain thereof, comprising administering an effective amount of a compound of formula II or a pharmaceutically acceptable salt thereof.

Group III, claims 1, 2, 4-13, 15 16, 18, 19, 21 and 22, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain

thereof, comprising administering an effective amount of a compound of formula III or a pharmaceutically acceptable salt thereof.

Group IV, claims 1, 2, 4-13, 18, 19, 21 and 22, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain thereof, comprising administering an effective amount of a compound of formula IV or a pharmaceutically acceptable salt thereof.

Group V, claims 1, 2, 4-13, 18, 19, 21 and 22, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain thereof, comprising administering an effective amount of a compound of formula V or a pharmaceutically acceptable salt thereof.

Group VI, claims 1, 2, 4-13, 18, 19, 21 and 22, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain thereof, comprising administering an effective amount of a compound of formula VI or a pharmaceutically acceptable salt thereof.

Group VII, claims 1, 2, 4-13, 18, 19, 21 and 22, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain thereof, comprising administering an effective amount of a compound of formula VII or a pharmaceutically acceptable salt thereof.

Group VIII, claims 1, 2, 4-13, 18, 19, 21 and 22, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain thereof, comprising administering an effective amount of a compound of formula VIII or a pharmaceutically acceptable salt thereof.

Group IX, claims 1, 2, 4-13, 18, 19, 21 and 22, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain thereof, comprising administering an effective amount of a compound of formula IX or a pharmaceutically acceptable salt thereof.

Group X, claims 1, 2, 4-13, 18, and 19, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain thereof, comprising administering an effective amount of a compound of formula X or a pharmaceutically acceptable salt thereof.

Group XI, claims 1, 2, 4-11, 18, and 19, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain thereof, comprising administering an effective amount of a compound of formula XI or a pharmaceutically acceptable salt thereof.

Group XII, claims 1, 2, 4-11, 18, and 19, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting

hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain thereof, comprising administering an effective amount of a compound of formula XII or a pharmaceutically acceptable salt thereof.

Group XIII, claims 1, 2, 4-11, 18, and 19, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain thereof, comprising administering an effective amount of a compound of formula XIII or a pharmaceutically acceptable salt thereof.

Group XIV, claims 1, 2, 4-11, 18, and 19, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain thereof, comprising administering an effective amount of a compound of formula XIV or a pharmaceutically acceptable salt thereof.

Group XV, claims 1, 2, 4-11, 18, and 19, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain thereof, comprising administering an effective amount of a compound of formula XV or a pharmaceutically acceptable salt thereof.

Group XVI, claims 1, 2, 4-11, 18, and 19, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular

binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain thereof, comprising administering an effective amount of a compound of formula XVI or a pharmaceutically acceptable salt thereof.

Group XVII, claims 1, 2, 4-11, 18, and 19, drawn to a method of achieving an immunomodulatory effect, achieving an antineoplastic effect, or inhibiting hyperproliferative cell growth in a patient in need thereof, and a method of modulating the binding of a $p56^{lck}$ molecule via an SH2 domain thereof to a corresponding cellular binding protein or modulating the activity of a $p56^{lck}$ molecule via an SH2 domain thereof, comprising administering an effective amount of a compound of formula XVII or a pharmaceutically acceptable salt thereof.

Group XVIII, claims 3, 14, 17, 20, and 23, drawn to a pharmaceutical composition comprising a compound of formula I or a pharmaceutically acceptable salt thereof.

Group XIX, claims 3, 14, 20, and 23, drawn to a pharmaceutical composition comprising a compound of formula II or a pharmaceutically acceptable salt thereof.

Group XX, claims 3, 14, 17, 20, and 23, drawn to a pharmaceutical composition comprising a compound of formula III or a pharmaceutically acceptable salt thereof.

Group XXI, claims 3, 14, 20, and 23, drawn to a pharmaceutical composition comprising a compound of formula IV or a pharmaceutically acceptable salt thereof.

Group XXII, claims 3, 14, 20, and 23, drawn to a pharmaceutical composition comprising a compound of formula V or a pharmaceutically acceptable salt thereof.

Group XXIII, claims 3, 14, 20, and 23, drawn to a pharmaceutical composition comprising a compound of formula VI or a pharmaceutically acceptable salt thereof.

Group XXIV, claims 3, 14, 20, and 23, drawn to a pharmaceutical composition comprising a compound of formula VII or a pharmaceutically acceptable salt thereof.

Group XXV, claims 3, 14, 20, and 23, drawn to a pharmaceutical composition comprising a compound of formula VIII or a pharmaceutically acceptable salt thereof.

Group XXVI, claims 3, 14, 20, and 23, drawn to a pharmaceutical composition comprising a compound of formula IX or a pharmaceutically acceptable salt thereof.

Group XXVII, claims 3, 14, and 20, drawn to a pharmaceutical composition comprising a compound of formula X or a pharmaceutically acceptable salt thereof.

Group XXVIII, claims 3 and 20, drawn to a pharmaceutical composition comprising a compound of formula XI or a pharmaceutically acceptable salt thereof.
Group XXIX, claims 3 and 20, drawn to a pharmaceutical composition comprising a compound of formula XII or a pharmaceutically acceptable salt thereof.
Group XXX, claims 3 and 20, drawn to a pharmaceutical composition comprising a compound of formula XIII or a pharmaceutically acceptable salt thereof.
Group XXXI, claims 3 and 20, drawn to a pharmaceutical composition comprising a compound of formula XIV or a pharmaceutically acceptable salt thereof.
Group XXXII, claims 3 and 20, drawn to a pharmaceutical composition comprising a compound of formula XV or a pharmaceutically acceptable salt thereof.
Group XXXIII, claims 3 and 20, drawn to a pharmaceutical composition comprising a compound of formula XVI or a pharmaceutically acceptable salt thereof.
Group XXXIV, claims 3 and 20, drawn to a pharmaceutical composition comprising a compound of formula XVII or a pharmaceutically acceptable salt thereof.

2. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: There is no single general inventive concept; the independent claims of Groups I-XXXIV require a compound defined by formulae I to XVII (i.e., 17 different formulae), while some dependent claims are limited to formulae I to IX (i.e., claims 21-23) and some are limited to lists of specific compounds (i.e., claims 12-17). Thus, there is no technical feature common to all claims.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Groups I-XVII requires the election from each of:

A single, specific compound, **including** identification of the values of each substituent variable of the appropriate structural formula;

A therapeutic effect (e.g., elect one of an immunomodulatory effect, an antineoplastic effect, or an inhibitory effect on hyperproliferative cell growth)

Groups XVIII-XXXIV requires the election of:

A single, specific compound, **including** identification of the values of each substituent variable of the appropriate structural formula.

Applicant is required, in reply to this action, to elect specie(s) as described above, to which the claims, which recite limitations to said species, shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Election of a specie not specifically disclosed as filed may be considered New Matter.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, all claims are generic:

The claims are deemed to correspond to the species listed above in the following manner:

All claims require an election of species

REQUIREMENT FOR UNITY OF INVENTION

4. As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention and species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does

not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1614

/James D Anderson/
Primary Examiner, Art Unit 1614